

REMARKS

After entry of this Amendment, the pending claims are: claims 16-32. The Advisory Action dated September 2, 2008 and the Final Office Action dated June 23, 2008 have been carefully considered. Claims 1-15 were previously canceled without prejudice. Claims 16, 18, 24, 25 and 32 have been amended to make explicit what was already implicit. Accordingly, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Final Office Action dated June 23, 2008, the Examiner:

- rejected claims 16, 17, 23-26 and 32 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,776,198 to Rabbe *et al.* (“Rabbe”);
- rejected claims 18-20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of U.S. Patent No. 6,899,734 to Castro *et al.* (“Castro”);
- rejected claim 21 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Castro and in further view of U.S. Patent No. 6,106,539 to Fortier (“Fortier”);
- rejected claims 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Castro; and
- rejected claim 30 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Castro and in further view of Fortier.

INDEPENDENT CLAIM 16

Independent claim 16 and dependent claims 17, 23 and 24, which are dependent on claim 16, have been rejected as being anticipated by Rabbe. Dependent claims 18-20 and 22 have been rejected as being unpatentable over Rabbe in view of Castro. Dependent claim 21 has been rejected as being unpatentable over Rabbe in view of Castro and in further view Fortier. Applicants respectfully traverse these rejections with respect to the above-listed claims.

Referring to Figs. 3 and 7-9, Rabbe discloses an adjustable vertebral body replacement assembly 20 including a cylindrical body 21 with external threads 32, threaded endplates 22 and end caps 23. Set screws 24 are provided for selectively fixing each endplate 22 to the threaded cylindrical body 21. The external threads 32 are configured to engage the threaded endplates 22 and each endplate 22 includes a bore 40 with internal threads 41 that mate with the external threads 32. The external threads 32 are cut in opposite directions so that the endplates 23 can be drawn together or apart by *rotating* only the threaded cylindrical body 21. Thus, as the threaded cylindrical body 21 is *rotated* in one direction, the threads 32 at each of the ends engage the internal threads 41 formed on the endplates 22 to move the endplates 22 closer or farther apart *so that the user can adjust the overall height of the implant*. The endplates 22 include spikes 91, 120 to penetrate the end plate of the adjacent vertebra to help maintain the position of the implant in situ and the spikes 91, 120 are constantly positioned on an opposite side of the endplates 22 from the cylindrical body 21. The end caps 23 span the bores 40 in the endplates 22 such that terminal ends of the cylindrical body 21 do not extend beyond an outer face of the endplates 22 or end caps 23 and do not contact end plates of the vertebrae in an implanted position.

In use, after the damaged vertebra is removed, the optimum vertebral height is determined and the threaded cylindrical body 21 and threaded endplates 22 are fitted together to achieve the proper height. Once the endplates 22 and threaded cylindrical body 21 have been adjusted to the correct height between the vertebrae, the set screws 24 are threaded into the threaded openings 39 formed in the endplates 22 so that the set screws 24 can engage and secure the threaded cylindrical body 21 with respect to the endplates 22. Thus, the set screws 24 provide a means for fixing the components together and for preventing rotation of the cylindrical body 21 with respect to either of the endplates 22.

The present application is directed to an intervertebral implant 15 including a spacer body having at least one endface 17 for contacting at least a portion of an adjacent vertebra and at least one end member 4 including a plurality of spikes 7 for engaging at least a portion of the adjacent vertebra. The at least one end member 4 is *non-rotatably, slidably movable* with respect to the spacer body so that the at least one end member 4 is *non-rotatably, slidably movable* between a first position and a second position. In the first position, the plurality of spikes 7 formed on the at least one end member 4 extend beyond the endface 17 of the spacer body and in the second position, the plurality of spikes 7 formed on the at least one end member 4 do not extend beyond the endface 17 of the spacer body.

Independent claim 16 of the present application is directed to an intervertebral implant and recites, as follows:

an intervertebral spacer body having at least an upper endface to contact at least a portion of an upper vertebra when in an implanted configuration; and at least one end member including a plurality of spikes for engaging at least a portion of the upper vertebra, wherein the at least one end

member is non-rotatably, slidably movable with respect to the intervertebral spacer body so that the at least one end member is non-rotatably, slidably moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the at least one end member extend beyond the upper endface of the spacer body and when in the second position the plurality of spikes formed on the at least one end member do not extend beyond the upper endface of the spacer body. (Emphasis added).

It is respectfully submitted that there is no disclosure, teaching or suggestion in Rabbe of an intervertebral implant comprising an intervertebral spacer body and at least one end member wherein the at least one end member is *non-rotatably, slidably movable* with respect to the intervertebral spacer body. Rather, at best, Rabbe discloses an intervertebral implant comprising a threaded cylindrical body 21 and a threaded endplate 22 that rotatably move relative to each other in order to translate so that the user can adjust the overall height of the implant.

Furthermore, it is respectfully submitted that there is no disclosure, teaching or suggestion in Rabbe of an intervertebral implant comprising an intervertebral spacer body and at least one end member wherein *the intervertebral spacer body includes an endface for contacting at least a portion of a vertebra*. Rather, Rabbe discloses an adjustable height intervertebral implant comprising a threaded cylindrical body 21 and a threaded endplate 22 wherein the threaded endplate 22 contacts the adjacent vertebra. There is no disclosure in Rabbe of the threaded cylindrical body 21 contacting the adjacent vertebra. In fact, such interpretation would be against the explicit teaching of Rabbe which is to provide an adjustable height implant with circular end faces 23 that cover the end faces of the cylindrical body 21, thereby preventing the body 21 from contacting the vertebral end plates. That is, it would be against

the explicit teachings of Rabbe to provide a cylindrical body 21 that contacts the adjacent vertebrae as this would eliminate the adjustable height feature disclosed in Rabbe.

Moreover, it is respectfully submitted that there is no disclosure, teaching or suggestion in Rabbe of an intervertebral implant comprising an intervertebral spacer body and at least one end member wherein the at least one end member is non-rotatably, slidably movable with respect to the intervertebral spacer body between a first position and a second position wherein in the first position the plurality of spikes formed on the at least one end member extend beyond the upper endface of the spacer body and in the second position the plurality of spikes formed on the at least one end member do not extend beyond the upper endface of the spacer body. There is no disclosure, teaching or suggestion in Rabbe of the endplates 22 and spikes 91, 120 being moveable between a first position wherein the spikes extend beyond the endface of the threaded cylindrical body 21 and a second position wherein the spikes do not extend beyond the endface of the threaded cylindrical body 21. It is respectfully submitted that the spikes in Rabbe always extend beyond the endface of the threaded cylindrical body 21.

Based upon each of the above-listed arguments, Applicants respectfully submit that Rabbe does not disclose, teach, or suggest all of the limitations of independent claim 16. Thus, it is respectfully submitted that independent claim 16 is allowable over Rabbe. Allowance of independent claim 16 is respectfully requested.

Furthermore, as claims 17-24 all depend from independent claim 16, it is submitted that these claims are equally allowable for at least these reasons. Withdrawal of these rejections and allowance of claims 17-24 is also respectfully requested.

With respect to claims 18-20 and 22 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Castro, it is respectfully submitted that Castro does not overcome the short comings of Rabbe. Castro was cited for the proposition that it would be obvious for one of ordinary skill in the art to incorporate one or more elastically deformable projections extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured. Without addressing the merits of this argument, it is respectfully submitted that, for at least the above-identified reasons, neither Rabbe nor Castro, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 16 and, therefore, dependent claims 18-20 and 22. Thus, it is respectfully submitted that dependent claims 18-20 and 22 are allowable over Rabbe and/or Castro. Withdrawal of these rejections and allowance of dependent claims 18-20 and 22 is respectfully requested.

With respect to claim 21 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Castro and in further view of Fortier, it is respectfully submitted that Fortier does not overcome the short comings of Rabbe and Castro. Fortier was cited for the proposition that it would be obvious for one of ordinary skill in the art to incorporate a shoulder on the spacer body for engaging one or more elastically deformable projections. Without addressing the merits of this argument, it is

respectfully submitted that, for at least the above-identified reasons, neither Rabbe, Castro nor Fortier, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 16 and, therefore, dependent claim 21. Thus, it is respectfully submitted that dependent claim 21 is allowable over Rabbe, Castro and/or Fortier. Withdrawal of this rejection and allowance of dependent claim 21 is respectfully requested.

INDEPENDENT CLAIM 25

Independent claim 25 and claim 26, which is dependent on claim 25, have been rejected as being anticipated by Rabbe. Dependent claims 27-29 and 31 have been rejected as being unpatentable over Rabbe in view of Castro. Dependent claim 30 has been rejected as being unpatentable over Rabbe in view of Castro and in further view Fortier. Applicants respectfully traverse these rejections with respect to the above-listed claims.

Independent claim 25 is directed to an intervertebral implant and recites, as follows:

an intervertebral spacer body having an upper endface to contact at least a portion of an upper vertebra when in an implanted configuration and a lower endface to contact at least a portion of a lower vertebra when in the implanted configuration; a first end member including a plurality of spikes for engaging at least a portion of the upper vertebra; and a second end member including a plurality of spikes for engaging at least a portion of the lower vertebra; wherein the first and second end members are non-rotatably, slidably movable with respect to the intervertebral spacer body so that the first and second end members are non-rotatably, slidably moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the first end member extend beyond the upper endface of the spacer body and the plurality of spikes formed on the second end member extend beyond the lower endface of the spacer body, and when in the

second position the plurality of spikes formed on the first end member do not extend beyond the upper endface and the plurality of spikes formed on the second end member do not extend beyond the lower endface. (Emphasis added).

For reasons similar to those listed above, it is respectfully submitted that Rabbe does not disclose, teach, or suggest all of the limitations of independent claim 25. Thus, it is respectfully submitted that independent claim 25 is allowable over Rabbe. Allowance of independent claim 25 is respectfully requested.

Furthermore, as claims 26-31 all depend from independent claim 25, it is submitted that these claims are equally allowable for at least these reasons. Withdrawal of these rejections and allowance of claims 26-31 is also respectfully requested.

INDEPENDENT CLAIM 32

Independent claim 32 has been rejected as being anticipated by Rabbe. Applicants respectfully traverse this rejection with respect to claim 32.

Independent claim 32 is directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae and recites as follows:

providing an intervertebral implant having an intervertebral spacer body having an upper endface and a lower endface for contacting the upper and lower vertebrae, respectively; and first and second end members, wherein the first and second end members are non-rotatably, slidably disposed on the intervertebral spacer body, the first and second end members including a plurality of spikes formed on a surface thereof; **inserting the intervertebral implant into the intervertebral disc so that the upper endface formed on the intervertebral spacer body contacts the upper vertebra and the lower endface formed on**

the intervertebral spacer body contacts the lower vertebra; non-rotatably, slidably moving the first and second end members with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively; and securing the first and second end members with respect to the intervertebral spacer body. (Emphasis Added).

For reasons similar to those listed above, it is respectfully submitted that Rabbe does not disclose, teach, or suggest all of the limitations of independent claim 32. Thus, it is respectfully submitted that independent claim 32 is allowable over Rabbe. Allowance of independent claim 32 is respectfully requested.

Application No. 10/552,675

Request for Continued Examination filed September 10, 2008

Response to Advisory Action dated September 2, 2008 and Final Office dated June 23, 2008

CONCLUSION

A fee of \$810.00 is believed due for this submission. The Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Respectfully submitted,

Date: September 10, 2008

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